University of Essex

PARTICIPANT INFORMATION SHEET

Department of Sport, Rehabilitation and Exercise Sciences, University of Essex

Non invasive optical assessment of the pathophysiology of concussion (mild traumatic brain injury) in adult rugby union players: toward improved health care

You are ~~is~~ being invited to take part in a research study on the use of a non invasive method to assess brain function during a season of rugby. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with your peers. Ask the lead researcher (Dr Ben Jones) if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this document.

Background of the research

Sport-related concussion (SRC) is a traumatic brain injury caused by external forces applied to the brain. Brain injury has devastating effects upon an individual and SRC is not well understood. It is suggested that repetitive concussive injuries increase the risk of neurodegenerative problems in later life ranging from mild brain impairments to neurological disease such as Dementia. Rugby union is, unfortunately, an ideal test sport to explore the impact of concussion. Over the course of one season, players can encounter up to 100 direct head impacts. Better understanding and measurement of brain function is needed to improve diagnosis and long term outcomes for players; this may also have significant benefits for other brain injury groups.

Functional Near-Infrared Spectroscopy (fNIRS) is a simple, non-invasive light based technology that can provide measurements of brain oxygenation. It relies on the relationship between brain blood flow and brain electrical signals to understand brain function. This research will directly compare brain function between individuals playing a season of rugby and a control group.

What is the aim of the study?

The principal aim is to use an objective and accurate method to assess the pathophysiology of sport-related concussion.

Why have I been invited to take part?

You have been invited to take part if you play competitive rugby or are physically active but do not take part in competitive contact sport and are aged between 18-35 years of age and male.

Who is carrying out the research?

The lead researcher for this project is Dr Ben Jones who is a senior lecturer at the University of Essex. He is a fully qualified rugby and strength and conditioning coach through the Rugby football Union and the National Strength and Conditioning Association and has multiple years of experience of working on sport related projects. He will be assisted by Dr Ed Hope a lecturer at the University of Essex in Performance Analysis, Professor Patrick Neary at the University of Regina, Professor Andrew Bateman from the University of Essex and postgraduate students from the University of Essex who will carry out data collection for the research project.

Who has reviewed this study?

The Ethics Sub Committee 2 of the University of Essex has reviewed and approved this study.

What will I be asked to do?

The study will last for one rugby season (July 2022 – July 2023) and will involve; completing the Sport Concussion Assessment Tool version 5 (SCAT5), the Neary Protocol an objective and non-invasive method to assess changes in cerebrovascular and cardiovascular physiology and cardiac monitoring on four occasions. Testing will take approximately 45 minutes and take place at Colchester Rugby Football Union Club for rugby players and at the University of Essex Sports Therapy Clinic for non-contact sport active controls. The SCAT5 is a standardised tool for evaluating concussions and involves you providing responses to questions regarding concussion symptoms, memory, concentration and a balance examination. The Neary protocol requires wearing a functional Near-Infrared Spectroscopy (fNIRS) brain monitor. The device is a portable, comfortable, non-invasive scalp (brain) covering that measures changes in brain oxygenation (figure 1).

You will complete computer based memory tasks, breathing challenges and sit to stand tests to challenge brain responses as part of the Neary protocol. Cardiac monitoring will take place wearing a cardiac sensor. This will involve placing a non-invasive sensor over the sternum of the chest that is held in place with a heart rate monitor band. The sensor is slightly larger than a two pound coin. The device records movement and measures the forces generated by the contraction and relaxation of the heart. You will be required to lie down in a restful position with a pillow under your head for 1-minute to relax completely before taking a 1-minute sample. Rugby players will also be asked to wear a small Global Positioning Satellite (GPS) unit during contact training sessions and games. This unit will be fitted on a vest and worn on your back between your shoulders and will collect impact and locomotive data.
Rugby players who suffer a concussive event will also be asked to complete the same measures i.e. SCAT5, Neary Protocol, and Cardiac Monitoring during their graduated return to play protocols, until they are able to return to match play.

Are there any risks involved?

There are no risks associated with taking the SCAT5, Neary Protocol, Cardiac monitoring or wearing the GPS units and minimal risks associated with taking part in the project overall. The minimal risk relates to the increased transmission of COVID from face to face contact. The research team will wear face masks, maintain social distancing where possible and carry out hand hygiene practices to minimise this risk.

Are there any benefits to my taking part?

This project utilises cutting edge neuroimaging technologies to investigate repeated measurements of brain function across a rugby playing season. Establishing the cumulative burden of concussive and sub-concussive injuries across a season will identify the consequences of a playing season of rugby on brain health. This monitoring system will provide practitioners and clinicians with the capacity to monitor brain function rapidly and regularly. Knowledge of brain function profiles during a playing

season will enable scientists to determine the severity of concussive and sub-concussive injuries and enable clinicians to make objective, evidence based decisions on immediate and longer term player brain health. The research will form the basis for the future development of an objective, evidence based protocol to assist brain health rehabilitation.

How will my information be used and stored?

The data will be safely stored on the University of Essex cloud service (Box), which is password protected, and is accessible only to the Research and Investigators mentioned in this information sheet. All data will be anonymized upon finalization of the project. Once the data has been analyzed, we will store the data on the University of Essex's Institutional repository and on the Centre for Open Science's repository. The data will be used for research the results of which will be disseminated via peer-review journal articles and scientific conferences. When the system or its data has completed its purpose, has become redundant or is no longer needed, permanent deletion will be adopted to dispose back-up media or other stored data. Deletion protocols will be permanent and files will be non-retrievable. No cache will be kept; back-ups will be physically destroyed.

Will my data be kept confidential?

All data will be kept confidential and unique participant numbers will be allocated instead of using your name on any electronic files.

Do I have to take part in the study?

No. Participation is entirely voluntary. If you decide you want to take part you will be given this information sheet to keep and be asked to sign a consent form. You have the right to withdraw from the study at any time for whatever reason and without explanation or penalty. In order to do this, please inform the lead researcher of your wish to withdraw from the study. If you would like your personal data removed from the analysis, please indicate this. You will need to state your unique participant number as it is not possible for the research team to link your data to you without this.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Dr. Ben Jones on 07843352501 or bjonesa@essex.ac.uk.

Who can I contact if I wish to make a complaint on ethical grounds?

Dr. Ben Jones on 07843352501 or bjonesa@essex.ac.uk. or Dr Ruth Lowry SRES Director of Research on r.lowry@essex.ac.uk.

Can I talk with the researcher or manager prior to taking part in the study?

You may contact Dr. Ben Jones on 07843352501 or bjonesa@essex.ac.uk or Sarah Manning-Press, Research Governance and Planning Manager on 01206 873561 or sarahm@essex.ac.uk.